



**IMDRF**

International Medical  
Device Regulators Forum

# **IMDRF ToC Pilot**

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## Pilot Plan

- Pilot intended to evaluate RPS Table of Contents structure with real, live, regulatory submissions sent to multiple regions
- Previous evaluations used historical submissions, which had limitations
  - Limited samples involving more than one region
  - No specific guidelines for building submission pre-RPS



## Pilot Plan

- Each region has a classification matrix that sets out specific folder structure
- Manufacturer populates the structure with the relevant information



## Pilot Objectives

- Develop and validate documentation supporting the use of the ToC using industry feedback
- Identify potential challenges for industry and develop proposals to address them moving forward
- Provide industry and regulators with experience using ToC in a controlled setting



## Pilot Objectives

- Evaluate the proper usage of ToC headings and placement of documents within headings
- Identify additional ToC harmonization opportunities
- Establish and ensure ToC pilot technical guidelines are fit for purpose and harmonized amongst regions to the extent possible



## Participants

- Australia, Brazil, Canada, China, Europe, and the United States are participating regions
- Regional pilots are also currently being undertaken by some IMDRF members



## Pilot Status

- Pilot initiated October 1, 2015
- Expected to run for 1 year or until all objectives are met
- 22 requests received, 11 accepted
  - 10 nIVD, 1 IVD
- Teleconference convened early February to discuss first impressions
  - Only a few applications received to date
  - Still too early to draw any conclusions



# Industry Feedback

- Early feedback focused on technical limitations of ToC
  - Character limit
  - Length of folder names
  - Requiring numerous sub-headers instead of amalgamating under one





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## Pilot Status

- Pilot and regional information for potential participants now posted on IMDRF website
- Certain regions discussing if scope should be expanded to encourage more submissions



## Pilot Status

- Application breakdown by region:
  - Australia: 1
  - Brazil: 10
  - Canada: 4
  - China: 4
  - EU: 3
  - USA: 5



## Next Steps

- Increase industry awareness of ToC Pilot and encourage more submissions
- Share pilot application experiences and discuss industry feedback amongst participating regions through regular meetings



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Questions?